TAB B

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 189 and 700

[Docket No. 2004N–0081]

RIN–0910–AF47

Use of Materials Derived From Cattle in Human Food and Cosmetics

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing an interim final rule (IFR) to prohibit the use of certain cattle material, [1] ~~because of the risk~~, [2] of bovine spongiform encephalopathy (BSE), in human food, including dietary supplements, and cosmetics. Prohibited cattle materials include specified risk materials, small intestine of all cattle, material from nonambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and mechanically separated (MS)(Beef). Specified risk materials are the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months and older; and the tonsils and distal ileum of the small intestine of all cattle. Prohibited cattle materials do not include tallow that contains no more than 0.15 percent hexane-insoluble impurities and tallow derivatives. FDA is taking this action in response to the finding of an adult cow that tested positive for BSE in the State of Washington. [3] This action is consistent with the recent interim final rule issued by the U.S. Department of Agriculture (USDA)

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Summary of Comments on G:\RES\SGML\CF0413.XML

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, imported from Canada,

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declaring specified risk materials and the carcasses and parts of nonambulatory disabled cattle to be inedible, unfit for human food, and prohibiting their use as human food and requiring that the entire small intestine be removed and disposed of as inedible. This action will minimize human exposure to materials that scientific studies have demonstrated contain the BSE agent in cattle infected with the disease. Scientists believe that the human disease variant Creutzfeldt-Jakob disease (vCJD) is likely caused by the consumption of products contaminated with the agent that causes BSE. Also in this issue of the **Federal Register**, FDA is proposing to require that manufacturers and processors of human food and cosmetics that are manufactured from, processed with, or otherwise contain material from cattle establish and maintain records sufficient to demonstrate that the food and cosmetics are in compliance with this interim final rule.

[1]

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DATES: The interim final rule is effective on [*insert date of publication in the* **Federal Register**]. Submit written or electronic comments by [*insert date 90 days after date of publication in the* **Federal Register**]. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in 21 CFR 189.5 and 700.27 as of [*insert date of publication in the* **Federal Register**].

ADDRESSES: You may submit comments, identified by Docket No. 2004N–0081, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

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are highly likely to

Since 1996, approximately 150 probable and confirmed cases of vCJD have been reported in the United Kingdom. In addition, one case of vCJD each has been reported in Ireland and Canada, both of which are believed to be related to BSE exposure in the United Kingdom. The one reported case of vCJD in the United States is also believed to be related to United Kingdom BSE exposure (Ref. 10). In addition, there have been 1 vCJD cases in France and one in Italy (Ref. 10). Because the incubation period for vCJD in humans may range from 5 to 20 years, some epidemiological models have projected that many more (600–3000) cases of vCJD caused by consumption of BSE-contaminated cattle products may occur in the United Kingdom in the future (Ref. 28).

D. BSE Risk Assessments

In 1998, USDA asked the Harvard Center for Risk Analysis (HCRA) and the Center for Computational Epidemiology at Tuskegee University to evaluate United States measures to prevent the spread of BSE to animals and humans if it were to occur in this country. The Harvard-Tuskegee risk assessment (referred to below as the Harvard-Tuskegee study) was published in November 2001, revised in 2003, and determined that the United States was highly resistant to any proliferation of BSE or a similar disease (Ref. 29). The risk assessment model also demonstrated that certain new control measures could reduce the small risk even further.

The Harvard-Tuskegee study involved a probabilistic simulation model to determine the consequences of introducing BSE into the U.S. cattle population. This simulation indicated that, in a hypothetical situation in which 10 infected cattle were imported into the United States, on average only four new cases of BSE would arise, and the disease would be eliminated in 20 years. The

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Based on the information presented previously and consistent with the USDA's regulation (69 FR 1862, January 12, 2004; discussed in section II of this document), we have determined that the tissues with the highest risk of harboring BSE infectivity (the SRMs) are the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of animals 30 months and older, and tonsil and distal ileum of cattle of all ages. Though the skull and the vertebral column have not been shown to harbor BSE infectivity, they contain tissues that have been shown to be infectious; therefore, we are including the skull and the vertebral column in the list of SRMs. We are not including the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum as SRMs with the rest of the vertebral column, because they do not contain spinal cord or dorsal root ganglia.

2. Animal Age at Which Tissues Become Infective

As discussed in the previous section, most tissues that harbor BSE infectivity have been shown to do so in animals more than 30 months after exposure to the agent. The exceptions are tonsils, which have been shown to harbor infectivity at low levels at 10 months post-exposure, and the distal ileum, which has been shown to harbor infectivity as early as 6 months post-exposure. In a study of the BSE epidemic in the United Kingdom, Dealler and Lacey (Ref. 32) noted that only 29 of 5,470 animals younger than 36 months of age developed BSE, with the peak number of cases occurring between 48 and 60 months of age. At the height of the BSE epidemic in the United Kingdom when thousands of animals were being diagnosed with BSE each year, fewer than 20 animals younger than 30 months [1] ~~showed signs of the~~ [2]

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were confirmed with the

disease (Ref. 33). The youngest animal with a confirmed case of BSE was 20 months old (Ref. 15).

Though animals younger than 30 months can develop BSE, it is 1 ~~ot a~~ 2 ~~mmon~~ occurrence, based on epidemiological and experimental evidence. 3 Therefore, we have concluded that brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia should be considered SRMs only in cattle 30 months and older.

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We are aware that there have been documented cases of BSE in animals younger than 30 months, and that some tissues become infectious before the animal exhibits clinical signs. As mentioned previously, during the height of the BSE epidemic in the United Kingdom, a small number of animals younger than 30 months showed signs of the disease. More recently, Japan has reported cases of BSE in 21- and 23-month-old animals, discovered during testing of animals presented for slaughter. As the science and epidemiology on this issue develop, FDA may find it necessary to modify the age period for SRM removal through future rulemaking.

Based on experimental evidence, we have concluded that the tonsil and distal ileum of the small intestine of all cattle should be considered SRMs.

F. Small Intestine

To ensure effective removal of the distal ileum, USDA is requiring that the entire small intestine be removed and disposed of as inedible product. FDA is also prohibiting the use of the entire small intestine in FDA-regulated food and cosmetics as prohibited cattle material. We are doing so because: (1) It is difficult to distinguish one end of the small intestine from the other once

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"Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle" (69 FR 1862). The rule declares that SRMs are inedible and unfit for food and prohibits their use as human food. The rule designates the following as SRMs: the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle. To ensure the distal ileum is completely removed, the entire intestine must be removed and disposed of as inedible. The rule also declares that MS(Beef) is unfit for food and inedible. In addition, the rule requires that all nonambulatory disabled cattle presented for slaughter be condemned and not used in human food. Furthermore, the rule requires that establishments that slaughter cattle or that process the carcasses or parts of carcasses of cattle maintain daily records sufficient to document the implementation and monitoring of procedures for removal, segregation, and disposition of SRMs. Finally, the rule deems all age-associated SRMs (all SRMs except tonsil and distal ileum) to be from animals 30 months or older unless an establishment can demonstrate that the materials are from an animal that was younger than 30 months of age at the time of slaughter.

In this interim final rule, FDA is extending similar protections to FDA-regulated human food and cosmetics. The USDA's FR will reduce but will not, by itself, eliminate the availability and use of prohibited cattle materials in domestic and imported FDA-regulated human food and cosmetics. Domestically, generally human food that contains meat only in a relatively small proportion or that historically has not been considered by consumers

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adulteration provisions of the act with respect to human food and cosmetics because of their failure immediately to establish and maintain the necessary records as of the effective date of this interim final rule. For that reason, we are proposing record establishment and maintenance requirements in a separate rulemaking, rather than including them in this IFR. Accordingly, in this issue of the **Federal Register**, we are proposing to require that those manufacturers and processor establish and maintain records to demonstrate compliance with this rule (see "Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing Material from Cattle"). Although the agency is pursuing a separate rulemaking on recordkeeping, we believe that some records may already be maintained that could provide the agency with valuable compliance information before a final rule on recordkeeping is issued as a result of the separate rulemaking. Therefore, we are requiring in this IFR that FDA be able to access already existing records that may demonstrate, or be relevant to, compliance with this rule.

E. Scope of the Interim Final Rule

The prohibitions contained in § 189.5 (b) apply to all FDA-regulated human food, except tallow and tallow derivatives. "Human food" is "food" as that term is defined in section 201(f) of the act (21 U.S.C. 321(f)), except for animal food. Specifically, "human food" is: (1) Articles used for food or drink for man, (2) chewing gum, and (3) articles used for components of any such article. "Human food" includes, but is not limited to, food additives, including substances that migrate into food from food packaging and other articles that contact food, color additives, dietary supplements and dietary ingredients, and infant formula.

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requirements (e.g., destruction or [1]se in inedible rendering, i.e., rendering for purposes other than human food), we assume that generally these materials are not likely to be widely available for use in the manufacture of FDA-regulated human food and cosmetics. The manufacturers and processors of products currently using materials that are considered SRMs (e.g., the brain, skull, spinal cord) would presumably be able to continue to use these ingredients, but exclusively from cattle younger than 30 months of age. The manufacturers of FDA-regulated human food products that use rendered material would continue to use rendered material that is the product of edible rendering (e.g., edible tallow). The manufacturers and processors of products using the tonsils and the small intestine of all cattle, material from nonambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and MS(Beef) would need to find substitutes for these ingredients. We assume that the recent USDA rulemaking has already led many of these manufacturers to search for alternative ingredients.

We do not have adequate information to quantify the cost of ingredient switching for human foods and request data on this subject. To the extent that this option leads to increased use of alternative ingredients, exposure to prohibited cattle materials will be reduced. Without a complete records requirement, however, the incentives to ensure that alternative ingredients are used are reduced. Access to existing records, as required by this option, would not increase the costs of this IFR, but would be beneficial in ensuring that acceptable cattle material is used in the manufacture of food and cosmetics.

Manufacturers of cosmetics that currently use inedible rendered materials, including tallow containing more than 0.15 percent hexane-insoluble impurities, would have to find alternative ingredients. We assume that they

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would be an extremely small amount compared to the total amount of waste generated by the cattle industry.

The agency has concluded that the IFR will not have a significant impact on the human environment, and that an environmental impact statement is not required. FDA's finding of no significant impact (FONSI) and the evidence supporting that finding, contained in an EA prepared under 21 CFR 25.40, may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday. FDA invites comments and submission of data concerning the EA and FONSI.

IX. Federalism

We have analyzed this IFR in accordance with the principles in Executive Order 13132. We have determined that the IFR does not contain policies that have substantial direct effects on the states, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we have concluded that the IFR does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement has not been prepared.

X. References

1. Johnson, R.T. and Gibbs, C.J. 1998, "Creutzfeldt-Jakob Disease and Related Transmissible Spongiform Encephalopathies," *New England Journal of Medicine*, 339 (27): 1994–2004.

2. Herzog, C, N. Sales, N. Etchegaray, et al., Tissue Distribution of Bovine Spongiform Encephalopathy Agent in Primates After Intravenous or Oral Infection, *Lancet*, 363 (9407): 422–28, 2004.

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and dorsal root ganglia of cattle 30 months and older and the tonsils and distal ileum of the small intestine of all cattle.

(6) *Tallow* means the rendered fat of cattle obtained by pressing or by applying any other extraction process to tissues derived directly from discrete adipose tissue masses or to other carcass parts and tissues. Tallow must be free of prohibited cattle risk material or must contain not more than 0.15 percent hexane-insoluble impurities determined by the method for "hexane-insoluble matter," p. 465, in the "Food Chemicals Codex," 5th Ed. (2003), incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or another method equivalent in accuracy, precision and sensitivity to the method in the Food Chemicals Codex.. You may obtain copies of the method from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418 (Internet address *http://www.nap.edu*) and the Division of Dairy and Egg Safety (HFS–306), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Copies may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(7) *Tallow derivative* means any chemical obtained through initial hydrolysis, saponification, or trans-esterification of tallow; chemical conversion of material obtained by hydrolysis, saponification, or trans-esterification may be applied to obtain the desired product.